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(54) **METAXALONE PRODUCTS, METHOD OF MANUFACTURE, AND METHOD OF USE**

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(52) **U.S. Cl.** ..... **514/376**

(58) **Field of Classification Search** ..... None  
See application file for complete search history.

(56) **References Cited**

#### **U.S. PATENT DOCUMENTS**

6,407,128 B1 6/2002 Scaife et al.  
6,683,102 B2 1/2004 Scaife et al.  
7,122,566 B1 \* 10/2006 Du et al. .... 514/376  
2004/0265889 A1 12/2004 Durham et al.

#### **OTHER PUBLICATIONS**

Medline Abstract No. 97217050, Kumar, Indian Journal of Experimental Biology, (May 1996) 34(5), 391-402.\*  
Medline Abstract No. 96432582, Oka et al., Japanese Journal of Pharmacology, (Jun. 1996) 71(2), 89-100.\*  
Medline Abstract No. 97074593, Smith et al., CA: A Cancer Journal for Clinicians, (Nov.-Dec. 1996), 46(6), 343-63.\*  
Medline Abstract No. 1998029329, Rickels et al., Journal of Clinical Psychiatry, (1997) 58 Suppl. 11, 4-10.\*  
Bynum, N.D., et al "Postmortem Distribution of Tramadol, Amitriptyline, and Their Metabolites in a Suicidal Overdose", Journal of Analytical Toxicology, 29(5): 401-406 (2005).  
Chou, R., et al "Comparative Efficacy and Safety of Skeletal Muscle Relaxants for Spasticity and Musculoskeletal Conditions: A systematic Review", J. Pain Symptom Management 28(2):140-75 (2004).  
Elenbaas, J. K. "Centrally Acting Oral Skeletal Muscle Relaxants", Am J Hosp Pharm. 37(10):1313-1323 (1980).

Gruszecki, A.C., et al "Polydrug Fatality Involving Metaxalone", J. Forensic Science 48(2): 432-4 (2003).

Kuykendall, J.R., et al "Auditory Hallucinations Elicited by Combined Meclizine and Metaxalone Use at Bedtime", Ann. Pharmacother. 38(11): 1968-1969 (2004).

Moore, K.A., et al "A Fatality Involving Metaxalone", Forensic Sci Int. 149 (2-3): 249-251 (2005).

Obach, R. S., et al "Human Liver Aldehyde Oxidase: Inhibition by 239 Drugs", Journal of Clinical Pharmacology 44(1): 7-19 (2004).

Poklis, J. L., et al "Metaxalone (Skelaxin)-Related Death", Journal of Analytical Toxicology 28(6): 537-540 (2004).

Schafer, Jr., E.W., et al "The Acute Oral Toxicity, Repellency, and Hazard Potential of 998 Chemicals to One or More Species of Wild and Domestic Birds", Archives of Environmental Contamination and Toxicology 12(3): 355-382 (1983).

Seidler, J., "Identification and Prediction of Promiscuous Aggregating Inhibitors Among Known Drugs", Journal of Medicinal Chemistry, 46(21): 4477-4486 (2003).

Toth, P.P., et al "Commonly Used Muscle Relaxant Therapies for Acute Low Back Pain: A Review of Carisoprodol, Cyclobenzaprine Hydrochloride, and Metaxalone", Clinical Therapeutics, 26(9): 1355-1367 (2004).

Prescribing Information for Skelaxin (metaxalone) as accessed at www.kingpharm.com on Dec. 21, 2005.

Sahi, J. et al "Comparative Effects of Thiazolidinediones on In Vitro P450 Enzyme Induction And Inhibition", The American Soc. For Pharmacology and Experimental Therapeutics, 31(4): 439-446 (2003).

"Norvir (ritonavir sulfate)", *Physicians' Desk Reference*, 58<sup>th</sup> Edition, 2004, Montvale, NJ, Thomson PDR, pp. 496-503.

"Crixivan (indinavir sulfate)", *Physicians' Desk Reference*, 58<sup>th</sup> Edition, 2004, Montvale, NJ, Thomson PDR, pp. 1957-1962.

Bynum ND, et al., "Postmortem Distribution of Tramadol, Amitriptyline, and Their Metabolites in a Suicidal Overdose" Journal of Analytical Toxicology, 29(5): 401-406 (2005).

Chou R, et al., "Comparative Efficacy and Safety of Skeletal Muscle Relaxants for Spasticity and Musculoskeletal Conditions: A Systematic Review", J. Pain Symptom Management 28(2):140-75 (2004).

Elenbaas JK, "Centrally Acting Oral Skeletal Muscle Relaxants," Am J Hosp Pharm. 37(10): 1313-1323 (1980).

Gruszecki AC, et al., "Polydrug Fatality Involving Metaxalone," J. Forensic Science 48(2): 432-4 (2003).

(Continued)

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(57) **ABSTRACT**

Disclosed herein is a method of using metaxalone. In one embodiment, the method comprises obtaining metaxalone from a container providing information that metaxalone affects the activity of a cytochrome p450 isozyme. In another embodiment, the method comprises informing a user that metaxalone affects the activity of a cytochrome p450 isozyme. Also included are articles of manufacture comprising a container containing a dosage form of metaxalone, wherein the container is associated with published material informing that metaxalone affects activity of a cytochrome p450 isozyme. Also disclosed are a method of treatment and a method of manufacturing a metaxalone product.

**8 Claims, No Drawings**